

I. The Office Action

The June 2, 2006 non-Final Office Action (the "Office Action") in this application rejected claims 16-21 and 36-44 under 35 U.S.C. 103 (a).

Applicants respond as follows.

II. Amendment to claims 16 and 39

Support for the amendment “provided in a dried state” in claims 16 and 39 can be found in the narratives found at least at page 14, lines 30-31 and at page 27, lines 10-11 of the specification.

Support for the amendment where the enhancing agent is “mixable with the stabilized botulinum toxin provided in a dried state” in claims 16 and 39 can be found in the narratives found at least at page 19, line 32-page 20, line 1 and at page 20 lines 22-25 of the specification.

III. Rejection of claims 16-21 and 36-44

The Office Action rejected claims 16-21 and 36-44 as unpatentable over Yuzhakov et al. (U.S. Patent 6,565,532, hereinafter "Yuzhakov") in view of Cevc (U.S. Patent 6,165,500, hereinafter "Cevc"). Applicant traverses this rejection.

The Office Action rejected the previously submitted claims on the grounds that Yuzhakov discloses a transdermal patch that includes a pharmaceutical composition, which could include botulinum toxin, an enhancing agent (polymer) and adhesive to hold the patch on place. The Office Action also asserts that Yuzhakov teaches a transdermal patch that includes a microneedle array which is projected or penetrates the stratum corneum. The Office Action states that Yuzhakov does not teach an enhancing agent is ethanol or comprises transfersomes (page 3, first line of Office Action).

Respectfully, Applicant asserts that the enhancing agent that the Office Action is referring to (polymers in col. 28, line 63) is directed to and is part of a list of materials by which the "closed-loop system" and body-fluid sampling sensors exemplified in Figures 30 and 31 of Yuzhakov, can be made of. The list of suitable material for construction of the "closed-loop system" further includes diamond, bio-compatible metal, ceramics, polymers, polymer composites (col. 28, lines 60-65. This was also detailed in Applicant's previous reply filed on 3/13/2006.

Solely and in order to facilitate prosecution, Applicant amends claims 16 and 39 to include to further define one aspect of the instant invention, namely the utilization of botulinum toxin in a dried state, and an enhancing agent that is mixable with the botulinum toxin recited in all of the claims. Since these amendments are made in all pending independent claims, all pending claims effectively incorporate this limitation.

There is no disclosure, either explicitly or implicitly, that can be found in either Yuzhakov or Cevc that relates to the use of a botulinum toxin in a dried state in conjunction with a transdermal patch, as presently claimed. Additionally, there is no teaching or suggestion in either Yuzhakov or Cevc that would suggest to one of ordinary skill in the art an enhancing agent that can be mixed with the botulinum toxin.

Enhancing agents in Yuzhakov are simply directed to the use of electric gradients and physical disruption (blades and needles) of the upper skin layers to deliver a material/drug through the skin. Cevc does not disclose or suggest the use of dried botulinum toxin in conjunction with a transdermal patch.

Additionally, Cevc contrasts the use of its compounds with typical methods for administration of a drug, stating that its disclosed compounds do away with the need and use of needles to introduce a dosage of a compound to a patient (see col. 5 lines 7-21) and that "... dermally applied transfersomes can thus successfully replace injections of insulin solutions". Cevc also proceeds to disclose the shortcomings associated with needle usage to administer compounds and how the transfersomes are "...used for non-invasive applications of antidiabetic agents, most frequently insulin..." (col. 70, lines 3-50). This disclosure teaches away from the use of compounds in Cevc in conjunction with needles and other conventional skin disruption/transdermal methods, such as the microneedle array of Yuzhakov and transdermal patches.

Accordingly, an obviousness rejection is improper, since the cited references do not provide evidence to support the combinations made by the Office Action, but rather, such combinations are made in the face of contrary teachings in the references and at best raise a suggestion of what would be "obvious to try", which is not a proper standard (In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed.Cir.1988)). A reference which teaches away from a claimed invention cannot be used to reject a claim *W.L. Gore & Associates, Inc.*

v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) (“...the district court erred in...disregarding disclosures in the references that diverge from and teach away from the invention at hand.” 220 USPQ at 311).

In fact, an enclosed printout from the IDEA AG website (the Assignee of the Cevc patent), further illustrates this teaching away, and contrasts the differences/effect and use of transfersomes in comparison to skin poration by electrical or mechanical means, such as those described in Yuzhakov (paragraph bridging pages 3-4 of Webpage <http://www.idea-ag.de/web/en/science/index.html>, attached).

It is only by utilizing the instant specification and claims in an exercise of hindsight reconstruction can the disparate teachings of Cevc and Yuzhakov be combined to assert obviousness of the claims in light thereof.

Thus, the rejection should be withdrawn.

IV. Conclusion

All issues raised in the Office Action have been addressed.
Reconsideration and allowance of claims 16-21 and 36-44 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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Attached: Webpage printout <http://www.idea-ag.de/web/en/science/index.html>